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10/574,337	05/09/2006	Seong Hwan Cho	1751-0400	8934

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EXAMINER	
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ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/574,337	CHO ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *16Feb10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are presented for examination.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's payment and submission filed February 5, 2010 was received and entered into the present application. Accordingly, prosecution has been reopened.

Claims 1-16 are pending and under examination. Claim 1 is amended.

Applicant's arguments, filed February 5, 2010, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Present claim 1 is directed to a sustained-release formulation comprising: (a) a sustained-release

core comprising an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions; (b) an enteric film coating layer coated on the sustained-release core; and (c) an active ingredient-containing film coating layer coated on the enteric film coating layer and comprising the active ingredient and a hydrophilic polymer for film coating, wherein the formulation is a multi-layer tablet.

In particular, the specification and claims as originally filed fail to provide adequate written description for the newly added limitation directed to wherein the sustained release formulation is a multi-layer tablet (claim 1).

Applicant references p.9-11 and the specification as a whole to provide written support for this newly added limitation. The disclosure at p.9-11 (and throughout the specification as a whole) describes the claimed sustained-release formulation in the form of a tablet, wherein the tablet contains various layers, including (i) the core layer comprising the active ingredient and polymer with erosion and swelling property in mammalian intestinal secretions, (ii) the enteric film coating layer coated onto the core layer, (iii) an active ingredient-containing film coating layer coated on the enteric film coating layer, and optionally (iv) an additional outer coating layer coated on the active ingredient-containing film coating layer.

While such teachings have been fully and carefully considered, it is noted that such disclosure fails to be supportive of the concept of the instantly claimed sustained release formulation in a "multi-layer tablet", wherein the number of layers are of any number. This disclosure that the instantly claimed composition may contain three layers (i.e., (i) the core layer comprising the active ingredient and polymer with erosion and swelling property in mammalian intestinal secretions, (ii) the enteric film coating layer coated onto the core layer, and (iii) an active ingredient-containing film coating layer coated on the enteric film coating layer) or possibly four layers (i.e., (i) the core layer comprising the active ingredient and polymer with erosion and swelling property in mammalian intestinal secretions, (ii) the enteric film

coating layer coated onto the core layer, (iii) an active ingredient-containing film coating layer coated on the enteric film coating layer, and (iv) an additional outer coating layer coated on the active ingredient-containing film coating layer) fails to provide clear written support to now claim that the instant sustained release composition may comprise *any* number of layers (e.g., two layers, 10 layers, etc.). This is a clear broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear from what is disclosed in the originally filed specification and claims that Applicant was not in possession of the concept of formulating the claimed sustained-release composition into a tablet with any number of layers (i.e., "multi-layer", which is interpreted as 2 or more), but rather was solely in possession of the concept of a tablet form comprising the instantly claimed sustained release composition that appears to have only three or four layers.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of wherein the sustained release formulation is a multi-layer tablet (claim 1).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 16 is directed to the sustained-release formulation of claim 15, wherein 60-99wt% of tamsulosin is contained in the sustained-release core and 1-40wt% of tamsulosin is contained in the active ingredient-containing film coating layer.

In particular, instant claim 16 is indefinite because it fails to set forth the basis for the percent calculation. For example, it is unclear whether the recited percentage range is percent by weight based on the total weight of the composition, percent by based on the weight of the sustained-release core alone, etc. Please see *Honeywell Intl. v. Intl. Trade Commn.*, 341 F.3d 1332, 1340 (Fed. Cir. 2003), where it was held that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the particular method of measurement is recited.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and is, thus, properly rejected.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda et al. (U.S. Patent Application Publication No. 2003/0147948; 2003).

Shinoda et al. teaches a composition comprising sustained-release fine particles, wherein the sustained-release fine particles are used to form quick-disintegrating tablets in the buccal cavity (abstract). Shinoda et al. teaches that the drug used in the disclosed formulation is not restricted as long as it is an active component requiring sustained releasability that is effective for treatment of a condition, and includes, *inter alia*, the BPH treating agent tamsulosin hydrochloride (p.4-5, para.[0051]). Shinoda et al. teaches that the sustained-release particles are formulated by layering the drug onto a core particle (i.e., commercial crystalline cellulose particles, crystalline lactose, granular sugar, sodium chloride, silicon dioxide, etc.) using a binder such as hydroxypropyl methylcellulose (i.e., which meets Applicant's claimed "polymer having erosion and swelling property in mammalian intestinal secretions" as recited in instant claims 1 and 3-6), wherein the particle is then further coated with a polymer substance, such as, *inter alia*, an enterosoluble polymer substance (i.e., which is defined at para.[0055] of Shinoda et al. to include enterosoluble acrylic acid copolymers, such as methacrylic acid-ethylacrylate copolymer) (p.8, para.[0074]). Shinoda et al. further discloses that a polymer substance with drug may be layered onto the particles to make a sustained release particle, wherein Shinoda et al. teaches that substances, such as, *inter alia*, polyvinyl alcohol may be mixed with the polymer components (i.e., which meets Applicant's part (c) of the claimed formulation, wherein polyvinyl alcohol is the hydrophilic polymer for film coating) and the particles may then be given enterosoluble function by coating with an enterosoluble polymer base as necessary (of which Shinoda et al. explicitly teaches methacrylic acid-ethylacrylate copolymer at para.[0055] as an enterosoluble polymer) (p.8, para.[0074]). Shinoda et al. further discloses that the amount of drug, percentage and amount of polymer substance, and the like, used for the coating(s) can be

adjusted as needed in accordance with the desired speed of dissolution (p.8, para.[0074]) and additionally teaches that the tabletting process using the described sustained-release particles to form a tablet preparation can be performed by conventional methods (p.9, para.[0079-0080]). Though it is noted that Shinoda et al. does not expressly describe the disclosed tablet formulation comprising the disclosed sustained-release particles as a "multi-layer tablet" as instantly claimed, the very "multi-layer" nature of the sustained-release particles is clear evidence that the tablet, as a whole, comprises multiple layers therein due to the presence of these layered particles, absent factual evidence to the contrary and further absent any description or requirement as to the specific structural configuration and/or arrangement of the "multi-layers" as instantly claimed.

Shinoda et al. fails to expressly teach that (1) the content of the polymer in the sustained-release core is 1-99 wt% based on the total weight of the sustained-release core (claim 7) or (2) that 60-99 wt% of tamsulosin is contained in the sustained-release core and 1-40wt% of tamsulosin is contained in the active ingredient-containing film coating layer (claim 16).

Regarding the instantly claimed amounts of polymer in the sustained-release core and the amount of tamsulosin contained in the sustained-release core and in the active ingredient-containing film coating layer (claims 7 or 16), Shinoda et al expressly teaches that, "The concentration of drug, percentage and amount of polymer substance, and the like, used for the coating can be adjusted as needed in accordance with the desired speed of dissolution." (p.8, para.[0074])

It is obvious from the above teachings that Shinoda et al. expressly contemplates variation in the amounts of both polymer and drug (i.e., active ingredient) employed in the disclosed sustained-release composition and specifically acknowledges that such a matter of adjusting the amounts was well within the skill of the artisan at the time of the invention and would not have required undue experimentation of have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not been

limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease to determine the amount of active ingredient necessary, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics, such as desired dissolution time, plasma concentrations, duration of action, etc., toxicology profiles of the particular compound employed, schedule of administration, etc. Thus, the amounts that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

In addition, the concentration of the polymer and/or active ingredient(s) is a result-effective variable, i.e., a variable that achieves a recognized result (i.e., wherein the polymer is employed as a binding agent and the active tamsulosin agent is employed for its BPH treating efficacy, as disclosed by Shinoda et al.), and, therefore, the determination of the optimum workable range of concentrations would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). Please see MPEP §2144.05[R-2](II)(A) and *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) ("[W]here the general conditions of claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.").

Conclusion

Rejection of claims 1-16 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Primary Examiner, Art Unit 1614

August 12, 2010